

JUN 2 8 2001

Section 2.0 510(k) Summary

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K010422

2.1 Submitted by

InnerSpace

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Contact: Donald E. Bobo ext 12

Prepared Feb. 8, 2001

This submittal covers a two-part system. Part 1 is an ICP monitoring system that includes a bolt with an integrated air-catheter and its accessory, a standard transducer in a housing mounted on a patient monitoring cable. The transducer is a class 1 device exempt from premarketing notification requirements. Part 2 is a ventricular catheter that can be introduced through the bolt if CSF drainage is needed.

2.2 ICP Monitoring Device Name

2.2.1 Trade name

ACT II ICP Monitoring System

2.2.2 Common name

Intracranial Pressure Monitoring Device

2.2.2 Classification name

Intracranial Pressure Monitoring Device
CFR 882.1620 (84GWM)

2.3 Ventricular Catheter Name

2.3.1 Trade name

ACT II Ventricular Catheter

2.3.2 Common name

Ventricular Catheter

2.3.3 Classification name

Ventricular Catheter
CFR 882.4100 (84HCA)

2.4 Equivalent device

The **ACT II ICP Monitoring System** is a substantially equivalent device to the Camino Micro Ventricular Bolt Pressure Monitoring system. It uses a bolt to mount an ICP device to the skull and places an ICP sensor in the parenchyma. The **ACT II Ventricular Catheter** is equivalent to drainage catheter portion of the Camino Micro Ventricular Bolt Pressure Monitoring system in that it is capable of draining CSF from a ventricle.

2.5 Description of the ICP Monitoring Device

The ICP monitor uses a bolt anchored in the skull. The bolt holds an air-column catheter with a flaccid bladder on the distal end. The proximal end of the catheter is attached to a pressure transducer placed in the distal end of a standard cable. The cable can be attached directly to any patient monitor. The ICP monitoring technology is based on Boyle's law. The bladder volume changes to accommodate $P_1V_1=P_2V_2$. The pressure in the bladder, catheter and transducer thereby mirrors that of ICP. The air required to activate the bladder is introduced into the bladder when a piston on the proximal end of the catheter is joined to a cylinder on the transducer housing. The bladder air is replaced once per shift by removing and replacing the transducer housing on the piston

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2.6 Description of the Ventricular Catheter

The catheter is a single lumen catheter. A preloaded stylet is used for catheter insertion and placement. A luer connector is provided to connect the catheter to a standard CSF collection system.

The bolt provides an access port through which a ventricular catheter can be introduced if drainage is needed. Should drainage of CSF be indicated, the top cap of the bolt is removed and the ACT II Ventricular Catheter is inserted into a ventricle. Once the catheter is in place, a preinstalled elastomeric sleeve and compression cap are moved down the catheter to the bolt. The cap compresses the sleeve against the bolt and catheter anchors the catheter in place.

The intent of the system design is to provide a minimally invasive ICP monitoring device to which a drainage capability can be added if needed.

2.7 Intended Use of the Device

The device is to be used in patients who require continuous ICP monitoring and who may require drainage of CSF.

2.8 Device Characteristics vs. Predicate Device

The essential characteristics of the ISM device vs. the predicate device are shown in table 1.

Table 1

Characteristic	ACT II	Predicate	Comment
Bolt diameter	.250"	.209"	
Skull Attachment	Ribs	Thread	Predicate bolt is screwed in a drill hole. ACT II is tapped in.
Pressure sensor OD	1.5 mm	1.35 mm	The 1.35 mm sensor is inserted into a 2.2 ID ventricular catheter
Catheter material	Urethane	Silicone	
Ventricular Catheter OD	2.7 mm	3.7 mm	
Ventricular Catheter ID	1.5 mm	2.2 mm	Predicate device flow path decreased by presence of 1.35 mm sensor.
Depth of pressure sensor in brain (ACT II) or in catheter (Camino)	1.3 cm	1-1.5 cm	
Depth of ventricular catheter in brain	6-8 cm	6-8 cm	
Bacteria barrier	Betadine on bolt/skull	Tunneled	
Transducer trouble shooting. See comment to right			Transducer of ACT II can be removed at any time to rezero monitor or replace sensor. Predicate sensor, in a lumen filled with CSF, is not removable.

2.9 Animal and Laboratory testing:

- The subject device meets AAMI performance standards.
- Animal test data of the subject device vs. a ventricular catheter shows the device faithfully follows the ventricular pressure and waveform and that the bolt is securely anchored in the skull.
- The biocompatibility of the **ACT II ICP Monitoring System** was tested per ISO 10993-1-1994 Biological Evaluation of Medical Devices – Part 1:

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Guidance on the Selection of Tests and the FDA General Program Memorandum No. G95-1. As regards the **ACT II Ventricular Catheter**, this submission relies on appropriate testing in accordance with ISO 10922-1 "Biological Testing of Medical and Dental Materials and Devices, Part 1: Guidance on Selection of Tests" and the "Tripartite Biocompatibility Guidelines for Medical Devices" as furnished by the material supplier.

Conclusion

The **ACT II ICP Monitoring System**, in combination with the **ISM -3000** series cable, and the **ACT II Ventricular Catheter** are equivalent to the predicate device because:

Intended Use

They have the same intended use, namely to sense intracranial pressure and drain CSF if needed.

Safety

Laboratory testing has shown that the **ACT II ICP Monitoring System**, the **ACT II Ventricular Catheter** and the **ISM -3000** series cable or pigtail are safe in the following areas:

- Mechanical integrity Laboratory testing and basic design assure that no parts will come loose and be left in the patient. The interference rib design provides a secure attachment to the skull.
- Biocompatibility The materials used in the **ACT II ICP Monitoring System** and **ACT II Ventricular Catheter** are safe for this application according to test results of a study performed by an independent third party and representations of material suppliers
- Patient trauma The system reduces the potential for patient trauma. The product has been designed to reduce tissue trauma in patients where the need for CSF drainage is not certain. The system can forgo placement of a more invasive ventricular catheter until the need for CSF drainage is established by observing ICP. The system thereby reduces patient trauma in those patients where the ICP level does not call for drainage.

Effectiveness

- Accuracy The ICP monitoring system meets AAMI standards for accuracy and performance.
- Ease of use The catheter is mounted in a bolt, as is the predicate device.
- Set up There is no need to precondition or calibrate the system beyond the normal zeroing of the transducer. The transducer connects directly to any patient monitor.
- Operating life The IFU requires that the air in the bladder be replaced every shift by removing and replacing the transducer on the piston.
- Trouble-shooting Unlike other in-situ systems, the transducer function and patient monitor zero can be checked at any time.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 28 2001

Mr. Donald E. Bobo
President
InnerSpace, Inc.
2933 South Pullman Street
Suite A
Santa Ana, California 92705

Re: K010422
Trade/Device Name: Act II ICP Monitoring System and Act II Ventricular Catheter
Regulation Number: 882.1620
Regulatory Class: II
Product Code: GWM
Dated: March 28, 2001
Received: April 2, 2001

Dear Mr. Bobo:

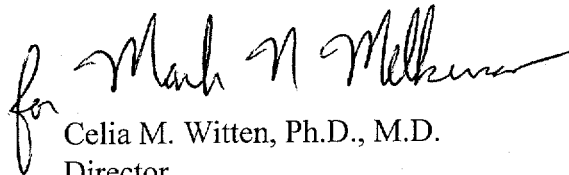
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.

Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment E

Indications for Use Statement

510(k) Number K010422

Device Name ACT II ICP Monitoring system

Indications For Use

ICP Monitoring system

Indications The use of the ACT II ICP Monitoring system by a qualified neurosurgeon is indicated when direct measurement of the intracranial pressure in the parenchyma is clinically important and when the patient may require CSF drainage in the course of their care.

Ventricular Catheter

Indications The use of an ACT II ventricular catheter by a qualified neurosurgeon is indicated when drainage of CSF is clinically important.

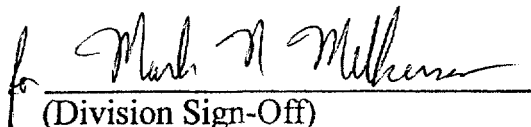
Please do not write below this line

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
 (Per 21 CFR 801.109)

Or

Over-The Counter Use ☐


(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number

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